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Subject: Evaluation of Intellicig electronic cigarette – (ECOpure Regular - Medium Strength Cartridge)

Background: To establish the position of the Intellicig electronic cigarette in the light of recent reports regarding various other electronic cigarettes. More specifically this is in regards to establishing whether small molecules are present in either the cartridge liquid or indeed the inhaled 'smoke form' which could be potentially undesirable to the user.

The Food and Drug Administration (FDA) of the Department of Health and Human Services of the United States Government recently reported a scripture relating to the evolution of tobacco impurities such as Ethylene Glycol (EG), Diethylene Glycol (DEG) and Tobacco Specific Nitrosamines (TSNA) which are supposedly emitted in micro quantities upon vaporisation of similar electronic cigarette products available in the United States.⁽¹⁾

Test Products:

Intellicig electronic cigarette (ECOpure Regular - Medium Strength Cartridge)

Conclusion:

The vaporised sample was achieved using a sparging apparatus (see picture below) using solvent conditions of water, acetonitrile phosphoric acid (800ml, 100ml, 11ml – 50ml of this solution) and pure acetonitrile. Over a ten minute period, 10 x 100ml of vapour was withdrawn and mixed with the solvent with each 100ml withdrawn over a period of 10 seconds. After 10 x 100ml samples a further 10 minutes mixing was allowed before samples were analysed by NMR, GCMS, LCMS.

¹H NMR spectroscopy, GCMS and LCMS was used to analyse the cartridge and also vaporised cigarette. Nicotine was shown to be present in all three forms of analysis along with glycerol. The ¹H NMR spectroscopy performed under solvent suppressed conditions revealed that the vaporised sample showed to contain only glycerol and nicotine in their pure unaltered molecular form. An aliquot (0.5ml) of these vaporised solutions was dissolved in deuterated acetonitrile and the NMR's were collected over an eight hour period. No other molecules apart from glycerol and nicotine were observed using a MESTREC NMR programme. This procedure was repeated using deuterated water as the NMR solvent with the same results as deuterated acetonitrile being observed. Since no other molecules representing possible impurities were present in the NMR it was deemed unnecessary to perform quantitative HS-GCMS analysis on the sample.

GCMS of the vaporised sample using the acetonitrile solvent in this sparging apparatus was also analysed under the conditions stated (see below 'conditions of column') The spectra revealed the presence of glycerol and nicotine and specifically did not show any indication on the MS of the reported TSNA impurities as observed by the referenced FDA publication. Likewise with GCMS the vaporised sample showed traces of glycerol in the MS but did not reveal any acrolein or the potential for EG / DEG.

LCMS of the vaporised cartridge showed that nicotine was present in its molecular form but did not give any indications of possible TSNA contaminants. For both GCMS and LCMS analysis a qualitative

approach rather than a quantitative approach has been employed at this stage but further work in this area will include HS-GCMS and HPLC-UV analysis for the determination of nicotine and glycerol concentrations per 100ml 'inhaled' sample.

Conditions of Nuclear Magnetic Resonance

400 MHz Avance NMR Machine

Solvent of samples: Deuterated acetonitrile (CD₃CN), deuterated water (D₂O).

Conditions of Liquid Chromatography Mass Spectrometry

Column: DB5-MS 30m 0.25 i.d. 0.25um (micro metre) film

Carrier Flow: 1.0 ml/min

Injection Volume: 0.2 ul (microlitre) split ratio of 100:1

Injection temp: 300°C

GC Programme: 50°C, 1.0 min hold, 10°C/min to 300°C, hold 10 mins.

Conditions of Gas Chromatography Mass Spectrometry

As per LCMS above.

	GCMS	NMR	LCMS
Tobacco Specific Nitrosamines			
NAB	Not Detected	Not Detected	Not Detected
NAT	Not Detected	Not Detected	Not Detected
NNK	Not Detected	Not Detected	Not Detected
NNN	Not Detected	Not Detected	Not Detected
Glycerol	Detected	Detected	Detected
Nicotine	Detected	Detected	Detected
Diethylene Glycol	Not Detected	Not Detected	Not Detected
Ethylene Glycol	Not Detected	Not Detected	Not Detected
Tobacco Specific impurities			
Cotinine	Not Detected	Not Detected	Not Detected
Anabasine	Not Detected	Not Detected	Not Detected
Myosmine	Not Detected	Not Detected	Not Detected
β-nicotyrine	Not Detected	Not Detected	Not Detected

NAB=N-nitrosoanabasine, NAT=N-nitrosoanatabine, NNK=4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone, NNN=N-nitrosornicotine These are potential tobacco specific impurities identified by the FDA.⁽¹⁾

NMR detection limit- 50 nmol. GCMS detection limit-100 nmol

Sparging apparatus used for extraction of Intellicig vapour



Reference 1: www.fda.gov/downloads/Drugs/ScienceResearch/UCM173250.pdf